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10/057,649	01/25/2002	Sverre Paaske	MEDIS-06906	3497

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EXAMINER

FLOOD, MICHELE C

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 02/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/057,649	<b>Applicant(s)</b> PAASKE ET AL.	
	<b>Examiner</b> Michele Flood	<b>Art Unit</b> 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 November 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 14-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Election/Restrictions***

Applicant's election without traverse of Group I, Claims 1-13, in the reply filed on November 18, 2004 is acknowledged. Further acknowledgment is made of Applicant's cancellation of Claims 14-31.

**Claims 1-13 are under examination.**

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites the phrase "wherein said microorganism is a fungi". The verb does not agree with the subject. Applicant may overcome the rejection by replacing "fungi" with fungus to place the claim in proper grammatical form.

Claim 3 recites the phrase "wherein said fungi is". The verb does not agree with the subject. Applicant may overcome the rejection by replacing "fungi" with fungus to place the claim in proper grammatical form.

With regard to Claim 6, lines 1-2, the phrase "comprises at least one bacteria" renders the claim grammatically incorrect. Applicant may overcome the rejection by replacing "bacteria" with bacterium to place the claim in proper grammatical form.

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Claim 7 recites the phrase "wherein said bacteria is". The verb does not agree with the subject. Applicant may overcome the rejection by replacing "bacteria" with bacterium to place the claim in proper grammatical form.

With regard to Claims 9 and 11, there is an apparent misspelling. Applicant may overcome the rejection by replacing "shizanda" with Schizandra.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5, 8 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Nishino et al. (N).

Applicant claims a dietary supplement growth medium from at least one microorganism. Applicant further claims the dietary supplement of claim 1, wherein said microorganism is a fungus; and, wherein said growth medium is dry growth medium. Applicant further claims the dietary supplement of claim 2, wherein said fungus is *Zygosaccharomyces*. Applicant further claims a foodstuff comprising the dietary supplement of claim 1.

Nishino teaches an antioxidant dietary supplement comprising growth medium cultures and their dried extracts from yeast, *e.g.*, *Candida stellatus*, *Candida parapsilosi*, *Rhodotorula rubra*, *Hypopichia burtoni*, *Zygosaccharomyces bisporus* or *Saccharomyces unisporus*. The antioxidant dietary supplement taught by Nishino can be used in the making of various foodstuffs. The reference antioxidants can suppress oxidation of low density lipoprotein (LDL) and can be used in the treatment of arteriosclerosis.

The reference anticipates the claimed subject matter.

Claims 1-6, 8 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Allen (U).

Applicant's claimed invention of Claims 1, 2, 5, 8 and 13 was set forth above. Applicant further claims the dietary supplement of claim 2, wherein said fungus is present as a co-culture. Applicant further claims the dietary supplement of claim 3, wherein said co-culture is a symbiotic co-culture; and, wherein said co-culture comprises at least one bacterium.

Allen teaches Kombucha or tea fungus as a symbiotic coculture of at least three microorganisms, such as the acetic acid bacteria *Acetobacter xylinum* and two yeasts *Zygosaccharomyces rouxii* and *Candida spp.* on sugared tea. On page 3, line 1, Allen teaches a powdered or dried Kombucha.

The reference anticipates the claimed subject matter.

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Claims 1-4, 6 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Shehata et al. (W).

Applicant's claimed invention of Claims 1-4 and 6 was set forth above. Applicant further claims the dietary supplement of claim 6, wherein said bacterium is selected from the group consisting of *Gluconacetobacter europaeus* and *Bacillus pumilus*.

Shehata teaches a dietary supplement comprising a filtrate obtained from *Bacillus pumilus* and a filtrate of *Streptococcus lactis* culture.

The reference anticipates the claimed subject matter.

Claims 1 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Naruse et al. (X) and Chacon Meijas (R).

Applicant's claimed invention was set forth above.

Naruse teaches fermentation growth medium broth comprising *Bacillus pumilus*, on page 288, lines 1-9. On pages 268-270, under "Extraction and Purification of Pumilacidin Complex", Naruse further teaches powder extracts of *Bacillus pumilus*.

Chacon Meijas teaches a dietary supplement comprising a growth medium of *Bacillus pumilus* used in the making of medicaments.

Each of the references anticipates the claimed subject matter.

Claims 1, 2, 8 and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Rekhif et al. (\*A).

Applicant's claimed invention was set forth above.

Rekhif teaches a food product comprising a dried fermentating agent of acetic acid present in the medium of a culture of *Gluconacetobater europaeus*. See entire document and patent claims.

The reference anticipates the claimed subject matter.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 5, 8-10 and 13 rejected under 35 U.S.C. 103(a) as being unpatentable over Nishino et al. (N) in view of Mishima et al. (O), Ri et al. (Q), Bae et al. (S), Hidvegi (Q) and Desser et al. (V).

Applicant's claimed invention of Claims 1, 2, 5, 8 and 13 was set forth above. Applicant further claims the dietary supplement of claim 8, wherein said supplement further comprises one or more additional components selected from the group consisting of dry red wine extract, *Schizandra*, alfalfa, and papain. Applicant further claims the dietary supplement of claim 9, wherein said supplement comprises dry growth medium and dry red wine at a ratio of approximately 2.35:1. Applicant further claims the dietary supplement of claim 9, wherein said supplement comprises dry growth medium and *Schizandra* extract at a ratio of approximately 4.7:1.

The teachings of Nishino are set forth above. Nishino teaches the instantly claimed dietary supplement except for the instantly claimed ingredients. However, it would have been obvious to one of ordinary skill in the art to add the claimed ingredients to the dietary supplement taught by Nishino to provide the instantly claimed invention because at the time the invention was made the claimed ingredients were known in the art for their beneficial health-promoting functional effects, as evidenced by the teachings of Mishima, Ri, Bae, Hidvegi and Desser. At the time the invention was made, one of ordinary skill would have been motivated and one would have been motivated and one would have had a reasonable expectation of success to add any of the instantly claimed ingredients to the composition taught by Mishima, Ri, Bae, Hidvegi and Desser to the composition taught by Nishino to provide the instantly claimed composition because the red wine extract taught by Mishima has antiarteriosclerotic, antilipemic and anticancer activities; the *Schizandra* extract taught by Ri is used in the making of pharmaceuticals having cholesterol-biosynthesis inhibitory activity, whereas the *Schizandra* extract taught by Bae provides high protection and treatment for cardiovascular disorders, such as hyperlipidemia, arteriosclerosis, which are induced by high levels of cholesterol in humans; the composition comprising an extract of alfalfa taught by Hidvegi exhibits blood-lipid level lowering activity; and, the compositions comprising papain taught by Desser were useful in treating diseases involving TGF-beta production, such as cancer.

Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add any of the claimed ingredients in the making of the



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claimed composition because it is well known that its *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten*, 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

As each of the references indicate that the various proportions and amounts of the ingredients used in the claimed composition or the claimed composition/pharmaceutical combinations are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

\* Applicant is advised that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site ([www.uspto.gov](http://www.uspto.gov)), from the Office of Public Records and from commercial sources. Should you receive inquiries about the use of the Office's PAIR system, applicants may be referred to the Electronic Business Center (EBC) at <http://www.uspto.gov/ebc/index.html> or 1-866-217-9197.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

  
**MICHELE FLOOD**  
**PATENT EXAMINER**

MCF  
February 4, 2005